

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

IN RE COLUMBIA UNIVERSITY  
PATENT LITIGATION

MDL No. 1592 (MLW)

This Document Relates To All Actions

**MEMORANDUM IN SUPPORT OF COLUMBIA UNIVERSITY'S EMERGENCY  
MOTION TO SEAL AND RESTRICT ACCESS TO CONFIDENTIAL INFORMATION**

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## PRELIMINARY STATEMENT

In their Reply in support of their Motion for a Preliminary Injunction, plaintiffs Biogen, Inc. (“Biogen”) and Genzyme Corp. (“Genzyme”) attached a document that is part of the confidential prosecution history of U.S. Patent Application No. 08/477,159 (the “’159 application”).<sup>1</sup> Defendant The Trustees of Columbia University in the City of New York (“Columbia”) is currently prosecuting the ’159 application in the U.S. Patent and Trademark Office (“PTO”). The Patent Act and PTO regulations protect the administrative record of proceedings involving the ’159 application (its “prosecution history”) from disclosure to any third party. There is no legal basis for Biogen and Genzyme somehow to have secured a portion of the confidential prosecution history of the ’159 application—and then place it in this Court’s public files. Indeed, as sophisticated patent-holders themselves, Biogen and Genzyme are well aware of the confidentiality rules that apply to the prosecution history of an unpublished patent application. Yet despite repeated inquiries, Biogen and Genzyme have defiantly refused to disclose how they obtained a portion of the confidential prosecution history of the ’159 application.

Columbia has asked the PTO to begin an investigation into how Biogen and Genzyme were able to obtain the confidential prosecution history of the ’159 application. Pending the outcome of this investigation, Columbia respectfully requests that the Court enter an order sealing the portions of the ’159 application prosecution history contained in the Biogen and Genzyme Reply and limit access to all portions of the ’159 application prosecution history to

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<sup>1</sup> The Biogen and Genzyme Joint Motion for a Preliminary Injunction is pending in *Biogen, Inc., Genzyme Corp., and Abbott Bioresearch Center, Inc. v. The Trustees of Columbia University in the City of New York*, Civil Action No. 03-CV-11320 (MLW), which is part of this consolidated proceeding.

outside attorneys for plaintiffs. In a conference call with all plaintiffs, Columbia requested that they stipulate to these minimal steps to protect Columbia's confidentiality rights pending the outcome of the PTO investigation. With the exception of Wyeth, which agreed to Columbia's confidentiality request pending the outcome of this motion, all plaintiffs refused.<sup>2</sup>

### **BACKGROUND**

On June 7, 1995, Columbia filed the '159 application in the PTO. Ex. B at 5. The application included a specification and a set of proposed claims delineating the scope of protection sought. After Columbia filed the '159 application, the PTO proceeded to examine it. That process involved an exchange of papers between Columbia and the PTO. For example, Columbia added, canceled and/or amended its proposed claims at various times during the proceedings. This collection of papers constitutes the prosecution history of the '159 application. The prosecution history is distinct from the original application filed on June 7, 1995.

On the same day that Columbia filed the '159 application, it also filed U.S. Patent Application No. 08/484,136 (the "136 application").<sup>3</sup> Columbia disclosed the existence of the '159 application during the PTO examination of the '136 application. Ex. A. at 2, 4. Columbia was not required to—and did not—submit the '159 application *prosecution history* documents to the examiner. The '136 application became U.S. Patent No. 6,455,275 (the "275 patent"). On

<sup>2</sup> Johnson & Johnson agreed to limit access to the documents to its "in-house litigation counsel" and outside counsel. Ex. H at 42-43. (All exhibits in this motion are attached to the Declaration of David Gindler filed herewith.) Genentech has agreed to limit access to the documents to "attorneys eyes only" but did not limit that access to outside counsel only. Ex. L at 49-50.

the front page of the '275 patent, the '159 application is listed as one of the references cited during the prosecution of the patent.<sup>4</sup>

On May 26, 2004, Biogen and Genzyme filed a Reply in support of their Motion for a Preliminary Injunction. Under Tab 3 of their Appendix they attached a substantial portion of a document dated October 23, 2003, from the '159 application's confidential prosecution history. In that document (the "Amendment"), Columbia proposed amendments to the claims under review by the PTO, proposed new claims, and explained why these claims are patentable. Tab 3 attaches the proposed amended claims and the proposed new claims.<sup>5</sup>

After Biogen and Genzyme released the confidential Amendment, Columbia requested a PTO investigation into how Biogen and Genzyme obtained portions of the confidential '159 application prosecution history. Gindler Decl. ¶ 21. Furthermore, in an attempt to resolve Columbia's concerns without resorting to motion practice, Columbia sent two letters to Biogen and Genzyme, the first one on May 27, 2004 (the day after they filed the Reply), asking them to explain how they obtained portions of the '159 application prosecution history and requesting that they "immediately make arrangements with the Court to prevent any entity from obtaining" the excerpts of the Amendment in the Appendix and Reply.<sup>6</sup> Ex. C at 31-32; Ex. F at 38-39.

<sup>3</sup> The '159 application and the '275 patent claim priority to the same original parent application. Gindler Decl. ¶ 4.

<sup>4</sup> The '275 patent lists the '159 application under the heading "Other Publications," Ex. B. at 5, and states that "all of the publications cited are hereby incorporated by reference." *Id.* at 29.

<sup>5</sup> Biogen and Genzyme also reproduced a portion of the Amendment in their Reply Memorandum in Support of their Preliminary Injunction Motion. Reply at 8-9.

<sup>6</sup> Columbia also requested that all the plaintiffs in this consolidated action destroy all portions of the '159 Application's prosecution history within their control and cooperate with Columbia in attempting to recover all portions of the prosecution history released to other

Biogen and Genzyme refused to comply with Columbia's request. Ex. E at 36-37; Ex. G at 40-41. In particular, they refused to disclose how they obtained a copy of the Amendment.

## **ARGUMENT**

### **A. The October 23, 2003 Amendment Is Confidential As a Matter of Law.**

Section 122 of the Patent Act requires that the prosecution history of the pending '159 application, including the portions of the Amendment contained in the Biogen and Genzyme Reply, remain confidential while Columbia prosecutes that application. Generally speaking, "applications for patents shall be kept in confidence by the Patent and Trademark Office and no information concerning the same given without authority of the applicant or owner . . ." 35 U.S.C. § 122(a). This confidentiality rule applies to documents in an application's prosecution history.<sup>7</sup>

Section 122(a) lists three exceptions to the confidentiality rule: (1) applications filed after November 29, 2000 are published 18 months after filing;<sup>8</sup> (2) the PTO may release an application or prosecution history if "necessary to carry out the provisions of an Act of

entities. Ex. C at 31-32; Ex. D at 33-34; Ex. I at 44-45. Once the PTO investigation concludes, Columbia may seek this and other additional relief from the Court.

<sup>7</sup> See, e.g., *Irons v. Diamond*, 670 F.2d 265, 268 (D.C. Cir. 1981) (PTO decisions on unpublished patent applications which are part of the prosecution history are subject to section 122); *Irons & Sears v. Dann*, 606 F.2d 1215, 1221 (D.C. Cir. 1979) (interim PTO decisions on pending applications are part of the prosecution history and are subject to section 122); *Misegades & Douglas v. Schuyler*, 328 F. Supp. 619, 620 (E.D. Va. 1971) (Section 122 "includes all pertinent information given the patent examiner by the inventor or his attorney pending the granting, denial or abandonment of his application").

<sup>8</sup> 35 U.S.C. § 122(b) requires the PTO to publish applications in certain circumstances. It only applies to applications filed after November 29, 2000. See Consolidated Appropriations Act, Pub. L. No. 106-113, §§ 4502(a), 4508, 113 Stat. 1501 ("Section[] 4502 β5 U.S.C. § 122(b)] . . . shall take effect on the date that is 1 year after the date of enactment of this act [November 29, 1999] and shall apply to all applications filed . . . on or after that date . . .").

Congress”; and (3) the PTO may release an application or prosecution history “in such special circumstances as may be determined by the Director.” The first two exceptions do not apply to the ’159 application: Columbia filed the ’159 application before November 29, 2000<sup>9</sup> and there is no Act of Congress that requires the PTO to reveal publicly the contents of the ’159 application prosecution history.

The third exception, for “special circumstances,” also does not apply to the prosecution history of the ’159 application. The “special circumstances” that allow the PTO to release the prosecution history of an application are enumerated in the PTO regulations at 37 C.F.R. § 1.14 (2004). Section 1.14 lists six circumstances in which the “file contents” (*i.e.*, the prosecution history) of an application are available to the public. 37 C.F.R. § 1.14(a)(i)-(v), (vii). The ’159 application does not come within any of these exceptions: (1) the ’159 application has not issued as a patent nor been published as a statutory invention registration (§ 1.14(a)(1)(i)); (2) the ’159 application is not a published abandoned application (§ 1.14(a)(1)(ii)); (3) the ’159 application is not a published pending application (§ 1.14(a)(1)(iii)); (4) the ’159 application is not an unpublished abandoned application (§ 1.14(a)(1)(iv)); (5) no other patent or application claims the benefit of the ’159 application under 35 U.S.C. §§ 119(e), 120, 121 or 365 (§ 1.14(a)(1)(v)); and (6) Columbia has not granted Biogen and Genzyme (or any third party) authority to inspect the portions of the ’159 application disclosed in the Reply (§ 1.14(a)(1)(vii)). Gindler Decl. ¶¶ 14-19. In addition, Columbia is not aware of any instance in which the PTO exercised its

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<sup>9</sup> Columbia filed the ’159 application on June 7, 1995. Ex. B at 5.

authority under 37 C.F.R. § 1.14(1)(h) to release the '159 application.<sup>10</sup> To the contrary, the PTO recently confirmed that the '159 application is confidential. Ex. K at 47.

The '159 application is an unpublished pending application that was incorporated by reference into the '275 patent. As such, 37 C.F.R. § 1.14(a)(1)(vi) governs its status. Section 1.14(a)(1)(vi) states that, in the context of an unpublished pending application that is incorporated by reference, "the application as *originally filed*" is available to the public. (Emphasis added). Unlike the other provisions of section 1.14(a)(1), it does not state that the "file" or "file contents" (*i.e.*, the prosecution history) of the '159 application is publicly available. *See also Manual of Patent Examining Procedure* ("MPEP") (8th ed. 2003, Feb. 2003 Rev.) § 103, at 100-7 to 100-8 (incorporation by reference "constitutes a special circumstance . . . warranting that a copy of the *application-as-filed* be provided upon written request") (emphasis added). Thus, PTO regulations explicitly distinguish between the '159 application as filed on June 7, 1995, which is open to the public, and the application's prosecution history, which is not.

The PTO has considered whether the prosecution history of a pending patent application becomes publicly available when the application itself is a cited reference in a published patent, *i.e.*, the exact issue presented here. The PTO concluded that the prosecution history was confidential and could not be released. *In re Gallo*, 231 U.S.P.Q. 496, 496 (1986) (May 9, 1986 Comm'r Pat. & Trademarks). In *Gallo*, a petitioner sought access to an unpublished pending application and prosecution history file. The application had been incorporated by reference in a patent. *Id.* The Commissioner ruled that the petitioner was entitled to receive a copy of the

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<sup>10</sup> Columbia is aware that in at least one other instance, a third party obtained a portion of the '159 application by incorrectly representing to the PTO that the '159 application was abandoned. Ex. J at 46.

original application, but documents in the prosecution history would remain confidential. *Id.* The Commissioner stated that an “incorporation by reference is interpreted as a waiver of confidentiality of only the original disclosure and does not open the entire application to inspection.” *Id.* “The petitioner may not have access to the prosecution history of that application as it developed subsequent to April 23, 1984,” the filing date of the application.<sup>11</sup> *Id.*

The Patent Act, and PTO regulations and practice, all make clear that the prosecution history of the ’159 application is confidential and not available to the public. Indeed, the PTO recently confirmed that the ’159 application prosecution history is confidential. Ex. K at 47.

**B. Good Cause Exists to Place the Amendment Under Seal and to Restrict Access to that Amendment to Outside Counsel**

“[W]hen a party requests a seal order . . . a court must carefully balance the competing interests that are at stake in the particular case.” *Siedle v. Putnam Investments, Inc.*, 147 F.3d 7, 10 (1st Cir. 1998). The Court should grant Columbia’s motion to protect its confidential information because: (1) Courts routinely seal documents containing confidential information and restrict access to such documents to outside counsel; (2) Columbia will suffer significant competitive harms if the Court allows its confidential information to remain in the public domain, while plaintiffs will suffer no harm if the court grants this motion; and (3) granting Columbia’s motion is consistent with Congress’s express policy of maintaining the

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<sup>11</sup> PTO regulations in effect in 1986 stated that “access [will not] be given to or copies furnished of any pending application or papers relating thereto . . . unless the application has been identified by serial number in a published patent document . . . , in which case status information such as whether it is pending, abandoned or patented may be supplied, or unless it shall be necessary to the proper conduct of business before the Office or as provided by this part.” 37 C.F.R. § 1.14(a) (1986). The subsequent amendments to the regulations have made more explicit the *Gallo* rule that disclosure of a referenced application is limited to the application “as originally filed.” 37 C.F.R. § 1.14(a)(1)(vi) (2004).

confidentiality of patent prosecutions.

Although the public is generally entitled to view court records, “the right to inspect and copy judicial records is not absolute.” *Nixon v. Warner Communications, Inc.*, 435 U.S. 589, 598 (1978). “[A]ccess [to court files] has been denied where court files might have become a vehicle for improper purposes.” *Id.* Importantly, courts routinely seal portions of records containing confidential business information to prevent improper uses of that information. *See, e.g., id.* (“[C]ourts have refused to permit their files to serve . . . as sources of business information that might harm a litigant’s competitive standing.”) (citations omitted).

In *SmithKline Beecham Corp. v. Pentech Pharm., Inc.*, 261 F. Supp. 2d 1002, 1008 (N.D. Ill. 2003), Judge Posner held that certain portions of a settlement agreement should remain sealed, even though the agreement did not contain “trade secret” information *per se*. He noted that “[t]he reason for secrecy is that it contains information about terms and conditions of the distributorship arrangement that the . . . agreement creates that might give other firms an unearned competitive advantage—unearned because the issue of public disclosure arises from the adventitious circumstance of the agreement’s having become caught up in litigation and as a result having become filed in court.” *Id.* He concluded that the agreement “contain[ed] legitimately confidential information to which [the parties’] competitors should not be entitled and which the American public does not need to know in order to evaluate the handling of this litigation by the judiciary.” *Id.*

Similarly, courts routinely order that access to confidential documents be restricted to outside counsel. Federal Rule of Civil Procedure 26(c)(7) provides that “[u]pon motion by a party . . . the court . . . may make any order [requiring] . . . that a trade secret or other confidential research, development, or commercial information not be revealed or be revealed

only in a designated way[.]” Pursuant to that rule, “[p]rotective orders that limit access to certain documents to counsel and experts only are commonly entered in litigation involving trade secrets and other confidential research, development, or commercial information.” *Quotron Sys., Inc. v. Automatic Data Processing, Inc.*, 141 F.R.D. 37, 40 (S.D.N.Y. 1992). See, e.g., *GTE Prods. Corp. v. Gee*, 112 F.R.D. 169, 170-71 (D. Mass. 1986) (entering protective order restricting access to party’s commercial information to outside counsel and experts).

The Court should seal the parts of the Reply that disclose portions of the Amendment and it should restrict access to outside counsel in this consolidated proceeding to prevent Columbia from suffering significant commercial harm. The Congress and the PTO have determined that the public is not entitled to view the prosecution history of the ’159 application. This provides a significant advantage to Columbia in its attempts to license the ’159 application. The plaintiffs and other third parties must contend with the fact that the ’159 application may issue as a patent, and that they may infringe the claims in the patent, but they will not know this unless and until it happens. Biogen and Genzyme’s wrongful possession of the Amendment, and their intentional release of it to the public, upsets the balance that the Congress and the PTO struck between the interests of the public and the interests of patent applicants. Cf. *Iron & Sears*, 606 F.2d at 1221 (Allowing FOIA access to files in patent prosecution history “would jeopardize the patent system by permitting competitors to divine or actually to secure information concerning inventions prior to the issuance of a patent.”). The Amendment reveals the details of Columbia’s communications with the PTO to obtain a patent, and the contours of the claims it was seeking. With this additional information, third parties (including the plaintiffs) can better judge the value of a license to the ’159 application, giving them a material advantage in negotiations. As Judge Posner observed, the release of the Amendment gives those who would license the ’159

application “an unearned competitive advantage[.]” *SmithKline*, 261 F. Supp. 2d at 1008.

Section 122 manifests Congress’s determination that the benefits of maintaining confidentiality during the patent application process outweigh the public harms that may arise from a temporary non-disclosure of the prosecution history. In fact, Congress considers the right to confidentiality during PTO proceedings so significant that a person who violates the strictures of 35 U.S.C. § 122 is subject to criminal prosecution.<sup>12</sup> Allowing the portions of the Amendment contained in the Biogen and Genzyme Reply to remain public ignores the expressed intent of Congress and the PTO.

Additionally, plaintiffs will not suffer any prejudice were the Court to grant this motion. Plaintiffs may argue that the ’159 application prosecution history is relevant to the instant litigation, and therefore is discoverable. Once discovery commences, and once a protective order is in place limiting disclosure of confidential information, Columbia is prepared to address this contention. However, plaintiffs are not entitled to subvert the discovery process by improperly obtaining the ’159 application prosecution history from the PTO and then releasing parts of it to the public.

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<sup>12</sup> See MPEP § 101, at 100-3 (“[a]ll . . . [PTO] employees are legally obligated to preserve pending applications for patents in confidence until they are published or patented. . . . Suspension, removal, and even criminal penalties may be imposed for violations of [35 U.S.C. § 122 and 18 U.S.C. § 2071].”); 18 U.S.C. § 2071.

**CONCLUSION**

For the foregoing reasons, Columbia respectfully requests that the Court: (1) seal the parts of the Reply that disclose portions of the '159 application prosecution history pending the outcome of the PTO investigation; and (2) order all portions of the '159 application prosecution history confidential and accessible only to outside attorneys for plaintiffs.

Respectfully submitted,

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